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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/393,302 09/10/99 HOVANESSIAN A 03495.0166-0

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HM12/1205

EXAMINER

ZEMAN, R

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

12/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/393,302

Applicant(s)
Hovanessian et al.

Examiner
Robert A. Zeman

Group Art Unit
1645



☒ Responsive to communication(s) filed on Sep 10, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-23 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

The claims are rather confusing and have numerous multiple dependencies. To the extent the claims can be understood as presently drawn, the following restriction requirement is made.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to P40/PHAPIII V3 loop HIV-1 receptor protein and P30/PHAPI V3 loop HIV-1 receptor protein, classified in class 530, subclass 350.

Claim 1 generic to a plurality of disclosed patentably distinct species comprising P95/nucleolin V3 loop HIV-1 receptor protein, P40/PHAPIII V3 loop HIV-1 receptor protein and P30/PHAPI V3 loop HIV-1 receptor protein. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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- II. Claims 2-6, 9-10 and 13, drawn to V3 loop HIV receptor inhibitors comprising P95/nucleolin, P40/PHAPIII V3 loop HIV-1 receptor protein and P30/PHAPI V3 loop HIV-1 receptor protein and therapeutic compositions containing same, classified in class 530, subclass 300.

Claims 2-5, 9-10 and 13 generic to a plurality of disclosed patentably distinct species comprising V3 loop HIV-1 receptor inhibitors comprising P95/nucleolin, P40/PHAPIII V3 and/or P30/PHAPI. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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This application contains claims directed to the following patentably distinct species of the claimed invention: V3 loop HIV-1 receptor inhibitors comprising P95/nucleolin, P40/PHAPIII V3 or P30/PHAPI (Claims 6-8).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-5, 9-10 and 13 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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- III. Claims 2, 11-13, drawn to antibodies and therapeutic compositions containing same, classified in class 530, subclass 387.1.
- IV. Claim 14, drawn to a therapeutic composition containing a polynucleotide inhibitors, classified in class 536, subclass 23.5.
- V. Claim 15, drawn to method of altering protein expression, classified in class 514, subclass 44.
- VI. Claim 16, drawn to method for using insertion DNA for specific replacement, classified in class 514, subclass 44.
- VII. Claim 17, drawn to therapeutic composition comprising antisense polynucleotides, classified in class 536, subclass 23.1.
- VIII. Claim 18, drawn to method of screening inhibitors via a binding assay, classified in class 435, subclass 7.2.
- IX. Claim 19, drawn to method of screening modulators via protein expression, classified in class 435, subclass 39.
- X. Claim 20, drawn to method of screening protein expression via antibodies, classified in class 435, subclass 7.1.
- XI. Claim 21, drawn to method of detecting gene mutation, classified in class 435, subclass 91.2.
- XII. Claim 22, drawn to nucleic acid probe, classified in class 536, subclass 24.31.

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XIII. Claim 23, drawn to method of screening inhibitors via viral proteins, classified in class 435, subclass 5.

The inventions are distinct, each from the other because of the following reasons: .

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are separate and distinct as they comprise completely differing biochemical and immunological entities having differing properties and uses. Inventions I-II are drawn to polypeptides and inhibitors of said polypeptides, while Invention III is drawn to antibodies and Invention IV is drawn to nucleic acid compositions.

Inventions I-IV are separate and distinct from Inventions V-VI as the polypeptides and inhibitors of Inventions I-IV cannot be used in the methods of Invention V or VI.

Inventions I-IV are unrelated to Invention VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are separate and distinct as they comprise completely differing biochemical and immunological entities having differing properties and uses. Inventions I-II are drawn to polypeptides and inhibitors of said polypeptides, while Invention III is drawn to antibodies and

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anti-idiotypic antibodies, Invention IV is drawn to nucleic acid compositions and Invention VII is drawn to a therapeutic antisense composition.

Inventions I and XII are separate and distinct from Invention VIII as the polypeptides of Invention I and the nucleic acid probe of Invention XII cannot be used in the methods of Invention VIII.

Inventions II-IV and VII are related to Invention VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides of Invention II can be used in mapping studies, the antibodies of Inventions III can be used for protein purification, the nucleotides of Inventions IV and VII can be used in hybridization experiments and gene mapping studies.

Inventions I-II and IV, VII and XII are separate and distinct from Invention IX as the polypeptides of Invention I, the inhibitors of Invention II and the nucleic acids of Inventions IV, VII and XII cannot be used in the methods of Invention IX.

Invention III is related to Invention IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the antibodies of Invention III can be used for protein purification.

Inventions V and VI are separate and distinct from Invention IV as they are drawn to differing methods having different steps and leading to differing results.

... Inventions I-III are separate and distinct from Invention X as the polypeptides of Invention I, the inhibitors of Invention II and the antibodies of Invention III cannot be used in the methods of Invention X.

Inventions IV, VII and XII are related to Invention XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Inventions IV and VII can be used to make polypeptides and the probe of Invention XII can be used in an *in vitro* mutagenesis assay.

Inventions V-VI, VIII-X and Invention XIII are separate and distinct from Invention XI as they are drawn to differing methods having different steps and leading to differing results.

Inventions I-II and are related to Invention XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the proteins of Invention I and the peptides of Invention II can be used in mapping studies.

Inventions III, VII and XII are separate and distinct from Invention XIII as the antibodies of Inventions III and the polynucleotides of Inventions VII and XII cannot be used in the methods of Invention XIII.

Inventions V-VI and VIII-IX are separate and distinct from Invention XIII as they are drawn to differing methods having different steps and leading to differing results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

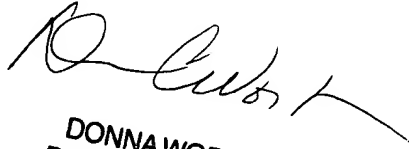
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.



DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

November 29, 2000